

31/ 33
34. (Amended) The method as claimed in claim 33 wherein said rubbery material consists essentially of a substance selected from the group consisting of trans-1,4-polybutadiene and its copolymers.

REMARKS

Reconsideration of the above-identified application in view of the amendment above and the remarks below is respectfully requested.

No claims have been canceled herein. Claims 1, 5, 9-11, 13, 31-46, 53 and 54 have been amended herein. No new claims have been added herein. Therefore, claims 1-6, 8-11 and 13-57 are pending. Of the pending claims, claims 2-4, 8-11, 14-16, 20-31, 33-45, 47-50, 52, 54, 55 and 57 are currently withdrawn from active consideration, and claims 1, 3, 5, 6, 13, 17-19, 32, 46, 51, 53 and 56 are under active consideration.

Claims 1, 3, 5-6, 13, 17-19, 32, 46, 51, 53 and 56 stand rejected under 35 U.S.C. 112, first paragraph, "as based on a disclosure which is not enabling." In support of the rejection, the Patent Office states the following:

The claimed rubber material having a transition temperature of 94-99°F is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Evidence that claims fail to correspond in scope with that which applicants regard as the invention can be found in Paper No. 22, filed May 9, 2000, in related US patent application 08/907,100. In that paper, applicant has stated that the Larson fabric support (US 5,807,291) does not have the claimed transition temperature (94-99°F) at which the claimed rubbery material shrinks from its second shape and size to its first shape and size. In the present specification Applicant's invention appears to be directed to that which will return to its original size or shape upon heating at or near the human body

temperature. Therefore, "the transition temperature in the range of 94 to 99 degrees Fahrenheit" should be recited accordingly.

Furthermore, the independent claims appear to be much broader in scope with respect to the transition temperature.

Applicants respectfully traverse the foregoing rejection. The Patent Office is apparently taking the position that "a transition temperature of 94-99°F is critical or essential to the practice of the invention" and, therefore, must be recited in the claims. Applicants respectfully disagree and submit that the Patent Office's position is supported neither by the present specification nor by the prosecution history of USSN 08/907,100 (of which the present application is a continuation).

The present specification is directed to (i) heat-shrinkable condoms, gloves, catheters and the like and/or (ii) hypo-allergenic condoms, gloves, catheters and the like. Although the present specification does make clear that the heat-shrinkable items must have a transition temperature, nowhere in the present specification is it stated that the transition temperature must be in the range of 94-99°F in order for the invention to work. Instead, the present specification clearly states that the transition temperature may or can be in the range of 94-99°F. See page 3, lines 18-19; page 8, lines 18-20, of the present specification. In addition, the present specification clearly contemplates that the transition temperature may not be in the range of 94-99°F, especially for items like gloves, by stating that "the transition temperature may be such that the gloves warm up to the transition temperature due to body heat alone, externally applied heat, special lighting, X-irradiation, or other methods of effectively heating an object." See page 8, line 24 through page 9, line 2, of the present specification. In fact, with respect to certain items, the present specification clearly states that the transition temperature may be outside the 94-99°F range. See page 9, lines 14-16; page 10, lines 17-20, of the present specification.

phrase does not
contemplate transition
range outside of 94-99°F
only that
heated from sources
other than
the human body

94-99
can be
from a
different
source
above or
below the
designed for
this range

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Moreover, nowhere in the prosecution history of USSN 08/907,100 (the parent application of the present application) do Applicants contend that it is critical that, for heat-shrinkable items to be operative, the transition temperature be in the range of 94-99°F. In the Amendment of May 9, 2000, which is cited by the Patent Office in the outstanding Office Action as the only evidence of the criticality of the 94-99°F range, Applicants merely stated that Larson et al. failed to render claim 1 obvious for, among other reasons, the reason that the fabric support of Larson et al. does not have the claimed transition temperature. Because the 94-99°F transition temperature limitation in question was not even recited in the claims at the time of the Amendment in question, clearly the import of the argument made in the Amendment was that the fabric support of Larson et al. did not have a transition temperature and not, as suggested by the Patent Office, that the fabric support of Larson et al. did not have a transition temperature of 94-99°F.¹ The 94-99°F transition temperature limitation was added to the claims later in the prosecution history only after the Patent Office indicated that it would place the claims in allowable form and would result in additional species being considered for patentability. It was only on this basis and without acquiescing in the propriety of the Patent Office's position that Applicants later added the 94-99°F transition temperature limitation to the claims.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

Claim 32 stands rejected under 35 U.S.C. 102(e) "as being anticipated by Beezhold (US 5563241)." In support of the rejection, the Patent Office states the following:

Beezhold teaches in the "Background of the Invention"
(column 1) that latex comprising about 33% rubber, 65% water and

¹ The Patent Office appears to acknowledge this construction of the passage in question in the Office Action of August 1, 2000 (see page 5, first full paragraph).

2% protein, also known as 1,4-cis-polyisopropene is used to make gloves. Although Beezhold teaches that this is naturally occurring, it is the examiner's position that the structure would be identical to that which Applicant is claiming as synthetic. Therefore, the claim has been met.

Applicants respectfully traverse the foregoing rejection. Claim 32 has been amended herein and now recites "[a] hypo-allergenic glove consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers."

Claim 32 is neither anticipated by nor rendered obvious over Beezhold for at least the reason that Beezhold does not teach or suggest a hypo-allergenic glove consisting essentially of a rubbery material recited in claim 32. Instead, Beezhold relates to a method of decreasing the amount of proteins in natural rubber latex and to articles, such as gloves, made with the treated natural rubber latex. According to Beezhold, itself, the Beezhold method does not result in the complete elimination of proteins from natural rubber latex. Rather, the Beezhold method still results in approximately 2-30% of the proteins remaining in the natural rubber latex. As pointed out both in Beezhold and in the present specification, the proteins in natural rubber latex are capable of provoking strong allergic reactions in some people. Consequently, a glove made by the Beezhold method cannot properly be considered a ^{no weight} hypo-allergenic glove consisting essentially of a rubbery material of the type recited in claim 32. Such proteinaceous impurities would materially affect the basic and novel qualities of such a glove and render said glove outside the scope of claim 32.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

Claims 1, 5, 6, 13, 46 and 53 stand rejected under 35 U.S.C. 102(b) "as being anticipated by Kuan et al. (US 4,891,409)." In support of the rejection, the Patent Office states the following:

not defined

"consisting essentially of"
MPEP 2111.02
C

Kuan et al. teaches a shape transformable composition comprising at least one crystalline polymer and at least one elastomer. The compositions are generally characterized by low glass transition temperatures ($<100^{\circ}\text{C}$), fairly compatible polymers and homogenous mixtures (column 1, lines 48-63). The compositions can be shaped transformed (stretched or compressed) under heat and retained in the transformed shape by cooling. Upon reheating, the compositions will return, or attempt to return to their original shape (state). Thus, the composition can be stretched or expanded under heat. Upon cooling, the compositions can be retained in the stretched or expanded state or permitted to partially shrink such that a partial expansion of the stretched state is retained. Upon reheating, the composition will shrink or be converted to its original state (column 2, lines 1-8). Suitable elastomers include non-crystalline random amorphous polymers including cis-1,4-polyisoprene either natural or synthetic (column 5, lines 49-59). Generally the crystalline component, the elastomer component, and the cross-linking agents are mixed together and heated to form a desired article.

polyisoprene
+ crystalline polymer
blend

Applicants respectfully traverse the foregoing rejection. Claim 1, from which claim 46 depends, has been amended herein and now recites “[a] rubbery material having a first shape and size, a second shape and size, and a transition temperature, wherein the rubbery material shrinks from the second shape and size toward the first shape and size after the application of energy to the rubbery material where the application of energy is equivalent in result to raising the rubbery material's temperature to at least the transition temperature wherein the rubbery material consists essentially of a substance selected from the group consisting of trans pentenamer and its copolymers, ethylene pimelate and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.”

Thus amended, claim 1 is neither anticipated by nor rendered obvious over Kuan et al. for at least the reason that Kuan et al. does not teach or suggest a rubbery material that, among other things, consists essentially of a substance selected from the group consisting of trans pentenamer

and its copolymers, ethylene pimelate and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers. Instead, Kuan et al. is directed to a composition that is a **blend** of one or more crystalline polymers and one or more elastomeric polymers, said blend endowing the composition with certain properties not possessed by the polymers individually.

Claim 5, from which claims 6 and 13 depend, and claim 53 are patentable over Kuan et al. for at least the same reasons given above for claim 1.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.

withdrawn
Claims 1, 3, 5-6, 13, 17-19, 32, 46, 51, 53 and 56 stand rejected "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6,221,447." In support of the rejection, the Patent Office states the following:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claimed invention is recited broadly enough to include or encompass that which is recited in related US Patent '447 with respect to additional article structure, e.g. condoms, wound cover, etc., and would include the more narrowly recited transition range of 94-99°F.

Applicants respectfully traverse the foregoing rejection. Without acquiescing in the propriety of the rejection, Applicants are submitting herewith a Terminal Disclaimer to obviate the rejection.

Accordingly, for at least the above reasons, the foregoing rejection should be withdrawn.


In conclusion, it is respectfully submitted that the present application is now in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is

required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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Dated: July 8, 2003

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 8, 2003



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Dated: July 8, 2003

MARKED-UP AMENDED CLAIMS 1, 5, 9-11, 13, 31-46, 53 AND 54

1. (Twice amended) A rubbery material having a first shape and size, a second shape and size, and a transition temperature, wherein the rubbery material shrinks from the second shape and size toward the first shape and size after the application of energy to the rubbery material where the application of energy is equivalent in result to raising the rubbery material's temperature to at least the transition temperature wherein the rubbery material [comprises] consists essentially of a substance selected from the group consisting of trans pentenamer and its copolymers, ethylene pimelate and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

5. (Twice amended) A method for the manufacture and use of a rubbery material having a transition temperature, the method comprising the steps of:

(i) manufacturing and cross-linking the rubbery material to a first shape and size, the rubbery material [comprising] consisting essentially of a substance selected from the group consisting of trans pentenamer and its copolymers, ethylene pimelate and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers;

(ii) after performing step (i), applying energy to the rubbery material, where the application of energy is equivalent in result to raising the rubbery material's temperature to at least the transition temperature;

(iii) after performing step (i), stretching the rubbery material to a second shape and size; wherein steps (ii) and (iii) are performed in such a way that the rubbery material is in a state in which it is both in the second shape and size and its effective temperature is at least the transition temperature; and

(iv) after steps (ii) and (iii) have been performed, reducing the effective temperature of the rubbery material below the transition temperature while the rubbery material is kept in the second shape and size so that the rubbery material remains in the second shape and size until subsequent application of energy to the rubbery material equivalent in result to raising its temperature to at least the transition temperature whereupon the rubbery material shrinks from the second shape and size toward the first shape and size.

9. (Amended) The method as set forth in claim 5, wherein the rubbery material [comprises] consists essentially of trans pentenamer and its copolymers.

10. (Amended) The method as set forth in claim 5, wherein the rubbery material [comprises] consists essentially of ethylene pimelate and its copolymers.

11. (Amended) The method as set forth in claim 5, wherein the rubbery material [comprises] consists essentially of trans-1,4-polybutadiene and its copolymers.

13. (Amended) The method as set forth in claim 5, wherein the rubbery material [comprises] consists essentially of synthetic cis-1,4-polyisoprene and its copolymers.

31. (Twice amended) A hypo-allergenic condom consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

32. (Twice amended) A hypo-allergenic glove consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

33. (Twice amended) [An] A hypo-allergenic oral-dental dam consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-

polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

34. (Twice amended) A hypo-allergenic stretchy-bandage consisting essentially of rubbery material selected from the group consisting of trans-1,4-polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

35. (Amended) A hypo-allergenic baby-bottle nipple consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

36. (Amended) A hypo-allergenic pacifier consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

37. (Twice amended) A hypo-allergenic catheter consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

38. (Twice amended) A hypo-allergenic tourniquet consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

39. (Amended) A hypo-allergenic dental drain consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and

its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

40. (Amended) [An] A hypo-allergenic injection port for intravenous lines and catheters, the injection port consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

41. (Amended) [An] A hypo-allergenic elastic band for articles of clothing, the elastic band consisting essentially of rubbery material selected from the group consisting of polybutadiene and its copolymers, trans-1,4-polybutadiene and its copolymers, synthetic isoprene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers.

42. (Twice amended) A rubbery material having a first shape and size, a second shape and size, and a transition temperature, wherein the rubbery material shrinks from the second shape and size toward the first shape and size after the application of energy to the rubbery material where the application of energy is equivalent in result to raising the rubbery material's temperature to at least the transition temperature, wherein the rubbery material [comprises a substance, said substance comprising] consists essentially of polyurethane elastomers and their copolymers.

43. (Amended) The rubbery material as claimed in claim 1 wherein said substance [comprises] consists essentially of trans pentenamer and its copolymers.

44. (Amended) The rubbery material as claimed in claim 1 wherein said substance [comprises] consists essentially of ethylene pimelate and its copolymers.

45. (Amended) The rubbery material as claimed in claim 1 wherein said substance [comprises] consists essentially of trans-1,4-polybutadiene and its copolymers.

46. (Amended) The rubbery material as claimed in claim 1 wherein said substance [comprises] consists essentially of synthetic cis-1,4-polyisoprene and its copolymers.

53. (Amended) A method of making a rubbery article, said method comprising the steps of:

(a) providing a rubbery material, said rubbery material [comprising] consisting essentially of a substance selected from the group consisting of trans pentenamer and its copolymers, ethylene pimelate and its copolymers, trans-1,4-polybutadiene and its copolymers, and synthetic cis-1,4-polyisoprene and its copolymers;

(b) manufacturing the rubbery material to a first shape and size;

(c) after step (b), cross-linking the rubbery material, the cross-linked rubbery material having a transition temperature;

(d) after step (c), applying energy to the cross-linked rubbery material, where the application of energy is equivalent in result to raising the cross-linked rubbery material's temperature to at least the transition temperature;

(e) after step (b), stretching the cross-linked rubbery material to a second shape and size, wherein steps (d) and (e) are performed in such a way that the cross-linked rubbery material is in a state in which it is both in the second shape and size and its effective temperature is at least the transition temperature; and

(f) after steps (d) and (e), reducing the effective temperature of the cross-linked rubbery material below the transition temperature while the cross-linked rubbery material is kept in the second shape and size so that the cross-linked rubbery material remains in the second shape and size until subsequent application of energy to the cross-linked rubbery material equivalent in result

to raising its temperature to at least the transition temperature whereupon the cross-linked rubbery material shrinks from the second shape and size toward the first shape and size.

54. (Amended) The method as claimed in claim 53 wherein said rubbery material [comprises] consists essentially of a substance selected from the group consisting of trans-1,4-polybutadiene and its copolymers.